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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/637,529

08/11/2000

Robert C. Beck

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EXAMINER

DESANTO, MATTHEW F

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

02/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/637,529	Applicant(s) BECK, ROBERT C.	
	Examiner MATTHEW F. DESANTO	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because there have been several interlineations or cancellations made in the specification or amendments to the claims which is confusing and could lead to a mistake during the issue and printing processes.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

The examiner also suggestions going through the specification and making sure all the reference number correspond to the correct drawing element. For exampled there are several areas where the control body is #16 and #17, as well as the cap being referred to as #19. Please correct the specification so that the examiner is able to fully understand applicant's invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 23 is rejected because applicant claims "said control body" but never recites this limitation into the claim prior to this. Therefore there is a lack of antecedent basis for the term "control body". The examiner interprets this claim with the term control body in the claim, but uses only the broad definition of the term control body.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 23, 24, 25, 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Ruggio (USPN 5,476,450).

Ruggio discloses a fluid supply catheter, a lumen, a distal aperture that is rounded in cross section (434) and other apertures (430+424), a control body (430) and

a sheath, wherein the ablation catheter is located within the sheath and adapted for motion with respect to the sheath and wherein said aperture defining a first aperture defining a first aperture direction for the emerging flow that lies between approximate zero degrees and ninety degrees (Figures 12, 13, 14, 15 and entire reference).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drasler et al. (USPN 5,496,267) and further in view of Ruggio (USPN 5,476,450).

Drasler et al. discloses a fluid supply catheter, a lumen, a distal aperture (460), and a sheath (448), wherein said aperture defining a first aperture defining a first aperture direction for the emerging flow that lies between approximate zero degrees and ninety degrees and a control body (452) has an outer surface that is used to mix high pressure fluid with embolic material (Figure 44 and Column 11, lines 13-64), but fails to disclose the distal end of the catheter is located within the sheath lumen.

Ruggio discloses the use of a delivery sheath and a therapeutic catheter for administering treatment to the patient (see figures 12-15).

Therefore, at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Drasler with Ruggio because Ruggio

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teaches the use of a guide catheter to be used since this allows for easier navigation then using several smaller tubes (Column 10 and 11). The examiner would also like to note that this modification would only take routine skill in the art since it is well known to use guide catheters to place a medical device in the body and that modifying the catheter to be able to move within a sheath is well known in the medical art, especially when the medical device has a distal end that can penetrate or pierce a vessel wall. Thus causing the medical device to be delivery through a tube.

9. Claim 19, 21-23, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drasler et al. (USPN 5,496,267) and further in view of Ruggio (USPN 5,476,450).

Drasler et al. discloses a fluid supply catheter, a lumen, a distal aperture (460), and a sheath (448), wherein said aperture defining a first aperture defining a first aperture direction for the emerging flow that lies between approximate zero degrees and ninety degrees and a control body (452) that has an outer surface that is used to mix high pressure fluid with embolic material (Figure 44 and Column 11, lines 13-64), but fails to disclose the aperture having a center on the catheter axis.

Ruggio discloses the use of a delivery sheath and a therapeutic catheter for administering treatment to the patient (see figures 12-15) as well as showing apertures that are located on the longitudinal axis as well as apertures that are radially located on the catheter wall.

Therefore at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Drasler et al. with the teachings of

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Ruggio to obtain the claimed invention. The device of Drasler et al. teaches the same concept as the applicant with the only difference being the orientation of the aperture. In Drasler et al. the catheter has an oversized control body and a catheter having a central lumen that transports fluid through it to an aperture. Drasler et al. also discloses retrograde flow as well as the possibility of the Coanda Effect, but the difference lies in the orientation and direction of the aperture. Applicant's invention teaches an aperture that is on the longitudinal axis of the catheter while Drasler et al. teaches an aperture that is angled. Ruggio discloses apertures that are on the longitudinal axis and apertures that are located at a 90 degree angle to the longitudinal axis. Therefore, one of ordinary skill in the art would be able to use routine skill in the art to modify the orientation and angle of an aperture of a catheter in order to better control fluid of the device. The examiner would also like to note that changing aperture shape and size as well as orientation is a well known modification in the medical catheter art.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 19, 21-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,129,698. Although the conflicting claims are not identical, they are not patentably distinct from each other because the USPN 6129698 teaches a catheter body, apertures, and a control body and how the fluid interacts with the control body (see claim 1).

Response to Arguments

12. Applicant's arguments filed 3/02/07 have been fully considered, but are moot due to new grounds of rejection. The previous 102 Rejection based on Drasler et al. has been withdrawn due to new 103 Rejection based on Drasler et al.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
February 19, 2008

/Matthew F DeSanto/
Primary Examiner, Art Unit 3763